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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,351	07/29/2003	Claes Gustafsson	MXGNP004X1/0311.310US	6357

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EXAMINER	
SKIBINSKY, ANNA	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,351	GUSTAFSSON ET AL.	
	Examiner	Art Unit	
	Anna Skibinsky	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-100* is/are pending in the application.

4a) Of the above claim(s) *1-75 and 82-100* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *13 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Election/Restriction

1. Applicant's election without traverse of group XI, claims 76-81, in the reply filed on April 12, 2006 is acknowledged.

2. Claims 1-75 and 82-100 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 12, 2006.

Objections to the Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

4. The hyperlinks are found on page 86, lines 25 and 31 and page 87, lines 3 and 4.

Claim Rejections - 35 USC § 101

Claims 76-81 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Said claims are toward a computer implemented method for the identifying of nucleotides for variation in a sequence to impact a desired activity. The method requires receiving data and an algorithmic process carried out by a computer program product, however the data is nontheless manipulated within a computer without a physical

manifestation. There is no visual displaying of results, transfer of data from a processor to a memory and no physical sample comprising sequences to be analyzed. Thus, these claims are non-statutory and do not produce a result which meet the standard of being concrete, tangible and useful.

The claims "must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception; which can be identified in various ways:

1) The claimed invention "transforms" an article or physical object to a different state or thing.

2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed in MPEP 2106, and See also:

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

The manipulation of coordinates and interaction energies or residues to calculate the crossover point is the manipulation of numbers, performed by the computer implementing programs and is therefore nonstatutory subject matter. Manipulation of data does not include a physical transformation outside of a computer or representation thereof. A process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter

and is not deemed to be concrete, tangible, and useful and is therefore non-statutory. An example which would make the instant method steps statutory would be to include a step of displaying the data for a user. Hence, the data would become concrete, tangible, and useful.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 76-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang et al. (US Pub. No. 2001/0051855; filed Feb. 16, 2001; claiming priority date Feb. 16, 2000).

7. The instant application pertains to a method for identifying amino acid residues for variation in a protein variant library. The identifying entails the characterization of a training set of protein variant sequences and determining which amino acids in the sequence have the greatest impact on the activity of the sequence.

8. Claim 76, step (a) recites data providing activity and nucleotide sequence information form each protein variant in a training set.

9. Wang et al. teach providing a parent sequence with properties of interest with residues that have a structural tolerance selected. Mutant polymers (i.e. variants) are created and then screened for properties of interest (i.e. activity) (paragraph 0023).

10. Claim 76, step (b) recites developing a model that predicts activity as a function of nucleotide types and position in the sequence.

11. Wang et al. teach identifying structurally tolerant residues in a polymer sequence where the mutation of the residues with high tolerance produce sequences with improved activity (paragraphs 0021, lines 10-22; and 0025). The tolerance is calculated for polymers of nucleic acids (paragraph 0132).

12. Claim 76, step (c) recites ranking positions in a nucleotide sequence or types at specific positions in order of impact on the desired activity.

13. Wang et al. teach quantifying the fitness (stability) of a sequence so that each amino acid will have a particular fitness value. Fitness is characterized as the extend to which a particular property (i.e. desired activity) of a polymer is optimized (paragraph 0083 to 0084).

14. Claim 77, step (d) recites ranking to identify nucleotides that are to be varied to impact the desired activity.

15. Want et al. teaches a method for selecting residues with structural tolerance for mutation to improve the certain properties of the sequence (paragraphs 0022 and 0083). Mutation of residues with structural tolerance lead to desired properties (paragraph 0021).

16. Claim 77 recites varying nucleotides which are codons.

17. Wang et al. teach the mutation of codons (paragraph 0014) and that the prior art is applied to polymers of nucleic acids (paragraph 0021) where genes can be modified directly or indirectly (paragraphs 150 and 154).

18. Claim 78 recites that the activity is a function of expression of nucleic acids.

19. Wang et al. teach the modification of parent amino acid sequences and expressing gene expression systems (paragraph 0154).

20. Claims 79-81 recite the method steps of claims 76-78 carried out by a computer program product.

21. Wang et al. teach the use of a computer system to carry out the described invention (Abstract; and paragraphs 160-171).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anna Skibinsky, PhD

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